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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/532,263	03/22/2000	Douglas James Hilton	10296A	8294

7590 06/10/2002

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400 Garden City Plaza  
Garden City, NY 11530

EXAMINER

PRASAD, SARADA C

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/532,263

Applicant(s)

HILTON, DOUGLAS JAMES

Examiner

Sarada C Prasad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/15/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5,8,9,11-15,17-21,24,25 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 13-15,17-21,24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,8,9,11,12 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,5,8,9,11-15,17-21,24,25 and 30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/702,665.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Detailed Action***

1. Receipt of Applicant's arguments and amendments filed in Paper No. 8 (4/15/02) is acknowledged. As per Applicant's request claims 3, 4, 26, 28, and 29 are cancelled, amendments to claims 1, 5, 8, 9, 12 have been entered. Currently claims 1, 5, 8, 9, 11-15, 17-21, 24-25 and 30 are pending; claims 13-15, 17-21, 24-25 have been withdrawn from consideration as being non-elected, and claims 1, 5, 8, 9, 11, 12, and 30 are under consideration for examination.
2. The following previous objections/rejections are withdrawn in light of Applicant's amendments filed in Paper No. 8 (4/15/02).
  - (i) change in title is acknowledged;
  - (ii) rejections of claims 1, 3, 4, 5, 8, 9, 11, 12 under 35 U.S.C. 112-first paragraph based on recitation of 'mutant, derivative, component, part, fragment, homologue, analogue or a peptide or polypeptide equivalent thereof....';
  - (iii) rejection of claims 9 and 26 under 35 U.S.C. 112-second paragraph based on recitation of 'capable of';
  - (iv) rejection of claim 1 under 35 U.S.C. 112-second paragraph based on recitation of 'derivative.....';
  - (v) rejection of claims 1, 3-5, 8-9, 11 under 35 U.S.C. 102(b) as being anticipated by WO 96/19574 (June 1996);
  - (vi) rejection of claims 12 and 29 under 35 U.S.C. 102(b) as being anticipated by Gorman et al. (1992);
  - (vii) rejection of claim 9 under 35 U.S.C. 112-second paragraph based on recitation of 'low stringency conditions';

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(viii) Applicant's arguments filed in Paper No. 8 (4/15/02), have been fully considered but were deemed persuasive in part. The issues remaining and new issues, are stated below. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Specification***

3. Applicant's intent to provide a substitute declaration is acknowledged, however until receipt of said declaration, the outstanding objection is maintained.

***Claim Rejections - 35 USC § 112-First Paragraph***

4a. Claims 1, 5, 12 remain rejected under 35 U.S.C. 112-first paragraph based on lack of enablement for reasons of record set forth in Paper No. 6 (10/10/01) and reiterated as follows. The new claim 30 is also rejected under this statute.

The rejection is based on the grounds that the specification is not enabling for recitation of '.....nucleotide sequence, which hybridizes to SEQ ID No. 4 or its complementary form under stringent hybridization conditions' as in claim 1, or '....said oligonucleotide is selected from SEQ ID No. 6-10 wherein said medium stringency conditions ....' in claim 12, or '....said nucleic acid further defined by the ability of an oligonucleotide to hybridize thereto under high stringency conditions ...' in claim 30.

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Applicant argues that these molecules are defined as IL-11 receptor alpha chain, which have definitive characteristics, and the applicant directs Examiner's attention to Examples 10, 12, 13, 15, and 16. Applicant maintains that the examples permit the skilled artisan to determine without undue experimentation whether a nucleic acid sequence encodes a polypeptide with characteristic features of an IL-11 receptor. Applicant also asserts that the example 10 describes

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the analysis of the deduced amino acid sequence that identifies motifs, domains and conserved residues characteristic of hematopoietin receptors, and examples 12, 13, 15, and 16 provide cell-based binding studies, and sequence analyses that confirm that the nucleic acid sequence encodes IL-11 receptor (page 5 of Paper No. 8, 2<sup>nd</sup> para). These arguments are not found to be persuasive for the following reasons.

In example 10, the Applicant points out (a) a deduced amino acid sequence of 432 amino acids including a potential hydrophobic leader sequence (residues 1-23), extracellular domain with two potential N-linked glycosylation sites (residues 24-367), transmembrane domain (residues 368-393) and short cytoplasmic tail (residues 394-432); (b) an extracellular domain consisting of residues characteristic to a classical haematopoietic domain, and (c) instant proposed IL-11 receptor  $\alpha$  chain exhibiting homology to IL-6 receptor  $\alpha$  chain, CTNF  $\alpha$  receptor and the p40 subunit of IL-12. One of skill in the art would not be able to use this information and generate claimed hybridization variants that would encode polypeptides with characteristics of instant IL-11 receptor  $\alpha$  chain in either binding to the ligand, and/or transducing the signal (agonists), or inhibit the binding (act as antagonists), because the described features are very general, and no correlation between any given domain, and a definitive function has been described in such a way as to render it predictable which hybridization variants would be

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reasonably expected to retain the features of the IL-11R  $\alpha$  chain. The above disclosed domains are proposed domains rather than shown to be required of at least one or a few of the claimed variants. In fact, predictability in the art points out that identification and characterization of orphan receptors as members of a specific family involves identifying required features of each polypeptide variant one at a time, rather than assuming that hybridization variants encode

polypeptides with desired functionalities. For example, Born et al. disclose two novel members of IL-1 receptor family. Toward this end, they compared the functionality of their transmembrane domains, extracellular domains and their cytoplasmic domains involving excessive amount of experimentation of producing chimeras of each of these domains in every possible combination, and eventually testing the functionality in terms of IL-1 stimulated transcriptional activation (page 29947, column 1, 2<sup>nd</sup> para), eventually only to find that these two novel members function as a new class of receptors within this family (abstract, last 2 lines). Furthermore, prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polynucleotides encompassed by the instant claims. Therefore, one of skill would reasonably conclude that it requires undue experimentation to practice the instant claims.

4b. Claims 1, 5, 12 remain rejected under 35 U.S.C. 112-first paragraph based on lack of adequate written description as set forth in Paper No. 6 (10/10/01) and reiterated as follows. The new claim 30 is also rejected under this statute.

Applicants argue that amendment to claim 1 would obviate the instant rejection. However, applicant's argument has not found to be persuasive because one of skill is not provided with a description which distinguishes which members of the genus of nucleic acids that hybridize under the claimed conditions encode for IL-11R  $\alpha$  chains, and are therefore species of the invention, and recite identifying characteristics of the nucleic acids in the context of the specification contemplating variants that might not be functional (page 4, line 15). The claims are broadly drawn to many hybridizable nucleic acid variants, while the specification describes a single nucleotide sequence of SEQ ID No. 4 encoding the instant polypeptide of SEQ

ID No. 5. The specification fails to describe any specific structural features of the claimed genus that would predictably correlate with a definitive IL-11R  $\alpha$  chain function such that the inventive species are adequately described.

Furthermore, pages 4 and 11 of specification disclose that the claimed IL-11R  $\alpha$  chains also encompass variants that do not need to retain function, for example, (a) see page 4-2<sup>nd</sup> para, line 15, "...whether functional or not.....", (b) page 11, 4<sup>th</sup> para, "...having identifying characteristics of the  $\alpha$  chain of the IL-11 receptor". Also, instant claims fail to recite any definitive characteristics expected of the IL-11R  $\alpha$  chains. Therefore, one of skill would reasonably conclude the applicants are not in possession of the claimed genus.

***Claim Rejections - 35 USC § 112 Second paragraph***

5. Claims 1, 5, 8-9, 11, 12 remain rejected under 35 USC § 112 second paragraph as set forth in item 4c of Paper No. 8 (4/15/02), as well as additional reasons reiterated as follows. Claim 30 is also rejected under this statute.

This rejection is based on recitation of

(a) 'a nucleotide sequence which hybridizes to SEQ ID No. 4 or its complementary form under high stringency hybridization conditions' in claim 1; (b) 'nucleic acid molecule further defined by the ability of an oligonucleotide to hybridize thereto under medium stringency conditions and wherein said oligonucleotide is selected from SEQ ID Nos. 6 to 10 wherein said medium stringency conditions comprise 0.25-0.5% w/v SDS at a greater than or equal to 45<sup>0</sup>C for 2-3 hours' in claim 12; and (c) 'defined by the ability of an oligonucleotide to hybridize thereto under high stringency conditions and wherein said oligonucleotide is selected from SEQ ID NO. 6 to 10' in claim 30.

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Applicants assert that they have amended claim 12 and further defined the parameters of the stringency conditions consistent with the disclosure found in the specification. Applicant maintains that specifically the claim now recites only specified medium stringency conditions to be consistent with the Examiner's recommendations (page 6, entire 5<sup>th</sup> para). However, these arguments are not found to be persuasive for the following reasons:

The nucleic acids that remain hybridized under defined hybridization conditions and wash conditions clearly set the metes and bounds of the complementary nucleic acids claimed. However, limitations such as moderate stringency, or high stringency recited in the instant claims are relative terms. A nucleotide fragment or a variant encoding SEQ ID No. 5-like polypeptide, which retains IL-11 receptor  $\alpha$  chain-like activity will require different hybridization conditions than would a 10- or 12-mer oligonucleotide being used as a probe such as SEQ ID Nos. 6-10. The term 'stringent hybridization conditions' denotes specific conditions in various situations and cannot be applied, generally to all DNA sequences uniformly. Further, since conditions such as DNA size, ionic strength, presence of formamide, time and molecular complexity combined with the degree of nucleotide complementarity and washing conditions determine the degree of hybridization, and in the instant case the reference made to Maniatis Manual in the specification (page 5, entire 3rd para) does not adequately define the 'stringency' conditions as claimed for SEQ ID No. 4 in claim 1, and SEQ ID Nos. 6-10 in claims 12 and 30.

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Claims 8, 9 are rejected insofar as they depend from rejected claim 1.

Amendment of instant claims by addition of specific supported hybridization conditions or removal of the hybridization language are two ways to overcome the instant grounds of rejection.



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***Conclusion***

6. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

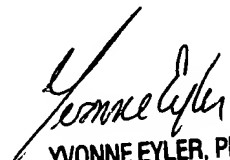
***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarawak C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Yeller, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Saudi Prasad, Ph.D.  
Examiner  
Art Unit 1646  
June 2<sup>nd</sup>, 2002.

  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
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